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36802 75	590 02/24/2005		EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER
 			3762	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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,		Application No.	Applicant(s)			
		10/045,844	ISAAC ET AL.			
	Office Action Summary	Examiner	Art Unit			
		Kristen Mullen	3762			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)🖾	Responsive to communication(s) filed on <u>02 D</u>	ecember 2004.				
2a)⊠	This action is FINAL . 2b) This	action is non-final.				
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
5)⊠ 6)⊠ 7)⊠	 4) Claim(s) 1-6,9,11-13 and 29-50 is/are pending in the application. 4a) Of the above claim(s) 9 is/are withdrawn from consideration. 5) Claim(s) 36 and 37 is/are allowed. 6) Claim(s) 1-2,4-512-13,29,32-35, 38-50 is/are rejected. 7) Claim(s) 3,6,11,30 and 31 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 					
Applicati	on Papers					
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on <u>08 November 2001</u> is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
2) Notice 3) Information	et(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

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DETAILED ACTION

Claim Objections

1. Claim 38 is objected to because of the following informalities: It appears that applicant accidentally included "a capacitor charge cycle defines a charge cycle time, and wherein" in line 13. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 32, and 43-46 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 4. Claim 32 recites the limitation "the capacitor charge cycle" in line 20 (line 1 of page 6 of the response). There is insufficient antecedent basis for this limitation in the claim.
- 5. Claim 43 recites the limitation "the charge cycle time" in line 10. There is insufficient antecedent basis for this limitation in the claim.

In claim 43, "the charge cycle time" is unclear, because it is unknown whether the charge cycle time is referring to the time required to charge the rechargeable battery, or the time required to charge the capacitors.

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Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 7. Claims 39-41, and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Munshi et al. (5,411,537).

Regarding claims 39, Munshi shows a method comprising charging storage capacitors with an LP battery (92), delivering electrical stimulation, and switchably connecting a supply battery (Col. 10, lines 43-51) to the LP battery to enable the supply battery (Col. 10, lines 43-51) to recharge the LP battery when voltage across the LP battery falls below a predetermined minimum (V_{min}) (Col. 9, lines 9-12, Col. 10, lines 66-68, Col.11, line 43-Col 12, line 16; Figs. 2-3).

With respect to claim 47, Munshi shows a method comprising charging storage capacitors with an LP battery (92), delivering electrical stimulation, and switchably connecting a supply battery (Col. 10, lines 43-51) to the LP battery to enable the supply battery (Col. 10, lines 43-51) to recharge the LP battery independent of the number of occurrences of delivering the electrical stimulation energy (Col. 10, lines 66-68, Col.11, lines 51-57, 62-65; Col 12, lines 12 16; Figs. 2-3).

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Regarding claims 40, and 48, Munshi shows the LP battery is Lithium Silver Vanadium Oxide (SVO) battery.

With respect to claims 41, and 49, it is inherent that the supply battery has a stored energy density greater than the stored energy density of the LP battery. Munshi discloses a rechargeable battery (92) part of a power supply that is utilized to provide power to pacing and defibrillation functions in an implantable device (Figs. 1-2). Although not specifically described, a power supply within an implantable cardioverter defibrillator is utilized to charge up capacitors which are utilized to discharge a high voltage defibrillation shock. The charging of the capacitors must take place quickly since defibrillation shocks must be administered as quickly as possible. An LP battery (92) such as disclosed by Munshi has a low energy density but is capable of charging capacitors very quickly. Energy density and ability to charge capacitors in a quick manner are roughly inversely proportional. Since the LP battery of Munshi must charge the defibrillator capacitors quickly it has a relatively low energy density.

Meanwhile, since the recharging of the LP battery by the supply battery does not have the same time constraints, it is inherent that the supply battery has a higher energy density due to the aforementioned inverse relationship.

8. Claims 38, and 47-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Howard et al. (6,650,942).

Regarding claims 38, and 47, Howard shows a device and method comprising a LP coupled to storage capacitors, the LP battery (60A, 60B) providing a charging current to charge the storage capacitors to a preselected energy level; a supply battery (62A, 62B) switchably connected (70, 80) in parallel to the LP battery and a recharging circuit (56A, 56B) coupled to

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the LP battery and configured to deliver charging current to the LP battery; wherein the recharging circuit periodically recharges the LP battery independent of the number of occurrences of the delivery of electrical stimulation energy (Col. 8, line 66- Col. 9, line 9).

Regarding claim 48-50, Howard shows the LP battery (60A, 60B) is Lithium Silver Vanadium Oxide (SVO) battery and the supply battery 62A, 62B) comprises a LiCFx battery, and the supply battery has a stored energy density greater that the LP battery (Col. 7, lines 19-35).

Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munshi et al. (5,411,537) in view of Kroll (5,741,307).

With respect to claim 43, Munshi shows a method comprising charging storage capacitors with an LP battery (92), delivering electrical stimulation, and switchably connecting a supply battery (Col. 10, lines 43-51) to the LP battery to enable the supply battery (Col. 10, lines 43-51) to recharge the LP battery. Although Munshi fails to teach recharging the LP battery when the capacitor charge cycle time exceeds a preselected value, attention is directed to Kroll which teaches measurement of the charge time in order to indicate inadequate battery strength (Fig. 2; Col. 3, lines 41-49). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method Munshi to include recharging

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the LP battery when the capacitor charge cycle time exceeds a preselected value, since Kroll teaches measuring of the charge time in order to indicate inadequate battery strength.

Regarding claim 44, Munshi shows the LP battery is Lithium Silver Vanadium Oxide (SVO) battery.

With respect to claim 45, it is inherent that the supply battery has a stored energy density greater than the stored energy density of the LP battery. Munshi discloses a rechargeable battery 92 part of a power supply that is utilized to provide power to pacing and defibrillation functions in an implantable device (Figs. 1-2). Although not specifically described, a power supply within an implantable cardioverter defibrillator is utilized to charge up capacitors which are utilized to discharge a high voltage defibrillation shock. The charging of the capacitors must take place quickly since defibrillation shocks must be administered as quickly as possible. An LP battery (92) such as disclosed by Munshi has a low energy density but is capable of charging capacitors very quickly. Energy density and ability to charge capacitors in a quick manner are roughly inversely proportional. Since the LP battery of Munshi must charge the defibrillator capacitors quickly it has a relatively low energy density. Meanwhile, since the recharging of the LP battery by the supply battery does not have the same time constraints, it is inherent that the supply battery has a higher energy density due to the aforementioned inverse relationship.

11. Claims 42, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munshi et al. (5,411,537). Munshi discloses the claimed invention except for the supply battery as disclosed in Col. 10, lines 42-51 comprises a an LiCFx battery. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to utilize a LiCFx battery for the supply battery of the Munshi, since applicant has not disclosed that this particular

battery composition provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any supply battery such as the supply battery taught by Munshi for charging the LP battery.

12. Claims 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Munshi et al. (5,411,537) in view of Kroll (5,741,307). Munshi and Kroll disclose the claimed invention except for the supply battery as disclosed in Col. 10, lines 42-51 comprises a an LiCFx battery. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to utilize a LiCFx battery for the supply battery of the Munshi and Kroll, since applicant has not disclosed that this particular battery composition provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any supply battery such as the supply battery taught by Munshi for charging the LP battery.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-2, 4-5, 12-13, 29, and 32-35 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 8 of U.S. Patent No. (6,549,807) in view of Kroll (5,741,307).

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With respect to claim 1, 4, and 29, although Kroll '807 fails to claim the controller is programmed to enable the second battery to recharge the first battery when the voltage across the first battery falls below a predetermined minimum value, attention is directed to Kroll '307 which teaches measurement of the voltage across a battery to determine when the voltage falls below a predetermined minimum value in order to indicate inadequate battery strength (Fig. 2; Col. 3, lines 14-40). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify device as claimed in Kroll '807 to be programmed to enable the second battery to recharge the first battery when the voltage across the first battery falls below a predetermined minimum value since Kroll '307 teaches measuring of the voltage across a battery to determine when the voltage falls below a predetermined minimum value in order to indicate inadequate battery strength.

Regarding claim 5, although Kroll '807 (as described above with respect to claim 1) fails to further claim a charging time interval detector, detecting the high voltage capacitor charge time and recharging the SVO battery when the charge time exceeds a preselected value, attention is directed to Kroll '307 which further teaches measurement of the charge time in order to indicate inadequate battery strength (Fig. 2, Col. 3, lines 41-49). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device as claimed by Kroll '807 as previously modified by Kroll '307 above to include a charge time interval detector, to detect the high voltage capacitor charge time and recharge the SVO battery when the charge time exceeds a preselected value, since Kroll '307 further teaches measuring of the charge time in order to indicate inadequate battery strength.

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With respect to claims 2, 12-13, 33-35, Kroll '807, further claims (in claims 8-9) the first battery comprises LiSVO, and the second battery comprises LiCFx.

Regarding claim 32, although Kroll '807 fails to claim (in claim 1) the controller is programmed to recharge the first battery when the charge cycle time exceeds a preselected value, attention is directed to Kroll '307 which teaches measurement of the charge time in order to indicate inadequate battery strength (Fig. 2; Col. 3, lines 41-49). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device as claimed in Kroll '807 to be programmed to recharge the first battery when the charge cycle time exceeds a preselected value, since Kroll '307 teaches measuring of the charge time in order to indicate inadequate battery strength.

Allowable Subject Matter

Claims 3, 6, 11, and 30-31, would be allowable if rewritten or amended to overcome the non-statutory Double Patenting rejection(s) set forth in this Office action.

Kroll (6,549,807) is no longer considered prior art under 35 U.S.C. 103(a).

With respect to claim 3, the prior art of record fails to teach or suggest a LP battery or first battery, and a supply battery or second battery switchably connected in parallel to the LP or first battery, a recharging circuit coupled to the LP or first battery, a controller programmed to enable the supply or second battery to recharge the LP or first battery when the voltage across the LP or first battery falls below a predetermined minimum value in combination with the LP being recharged upon the detection of a predetermined number of deliveries of stimulation energy.

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Regarding claim 6, the prior art of record fails to teach or suggest a LP battery or first battery, and a supply battery or second battery switchably connected in parallel to the LP or first battery, a recharging circuit coupled to the LP or first battery, a controller programmed to enable the supply or second battery to recharge the LP or first battery when the voltage across the LP or first battery falls below a predetermined minimum value in combination with the LP having a maximum energy capacity and where the LP is recharged at a rate les than a predetermined maximum charging rate.

With respect to claim 11, the prior art of record fails to teach or suggest a LP battery or first battery, and a supply battery or second battery switchably connected in parallel to the LP or first battery, a recharging circuit coupled to the LP or first battery, a controller programmed to enable the supply or second battery to recharge the LP or first battery when the voltage across the LP or first battery falls below a predetermined minimum value in combination with the supply battery having a greater stored energy density greater than the LP battery.

Regarding claim 30, the prior art fails to teach or suggest a device comprising a first battery switchably coupled to the charging circuitry, a second battery switchably connected in parallel to the first battery, a detector coupled to the charging circuitry that detects when the recharging current is above a predetermined threshold indicative of abnormal recharging within the first battery; a controller programmed to switchably enable the charging circuitry to produce the high voltage shocks, and to disable the second battery whenever an abnormal recharging current is detected, where the controller is programmed to enable the second battery to recharge the first battery when the voltage across the first battery falls below a predetermined minimum value all in combination with the first battery having a battery end of life and the controller is

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programmed to enable the second battery to recharge the first battery prior to reaching the end of life.

With respect to claim 31, the prior art fails to teach or suggest a device comprising a first battery switchably coupled to the charging circuitry, a second battery switchably connected in parallel to the first battery, a detector coupled to the charging circuitry that detects when the recharging current is above a predetermined threshold indicative of abnormal recharging within the first battery; a controller programmed to switchably enable the charging circuitry to produce the high voltage shocks, and to disable the second battery whenever an abnormal recharging current is detected, all in combination with the first battery charging the at least one capacitor in a capacitor charge cycle and wherein the controller is programmed to recharge the first battery upon the occurrence of a predetermined number of capacitor charge cycles.

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15. Claims 36-37 are allowed.

Regarding claim 36, the prior art fails to teach or suggest a device comprising a first battery switchably coupled to the charging circuitry, a second battery switchably connected in parallel to the first battery, a detector coupled to the charging circuitry that detects when the recharging current is above a predetermined threshold indicative of abnormal recharging within the first battery; a controller programmed to switchably enable the charging circuitry to produce the high voltage shocks, and to disable the second battery whenever an abnormal recharging current is detected, where the controller is programmed to enable the second battery to recharge the first battery when the voltage across the first battery falls below a predetermined minimum value all in combination with

With respect to claim 37, the prior art of record fails to teach or suggest a LP battery, and a supply battery switchably connected in parallel to the LP battery, a recharging circuit coupled to the LP battery in combination with a capacitor charge cycle defining a capacitor charge cycle time and the recharging circuit recharges the LP battery when the a charge cycle time exceeds a preselected value.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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